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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
CIPLA LTD., AUROBINDO PHARMA	:	
LLC, AUROBINDO PHARMA USA,	:	
INC., and AUROLIFE PHARMA LLC,	:	
	:	
Defendants.	:	
	:	

**PLAINTIFFS TEVA BRANDED PHARMACEUTICAL PRODUCTS
R&D, INC. AND NORTON (WATERFORD) LTD.'S POSTTRIAL
PROPOSED CONCLUSIONS OF LAW ADDRESSING VALIDITY**

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I. Presumption of Validity¹

A. Legal Standards

1. Under 35 U.S.C. § 282, a “patent shall be presumed valid.” To overcome this burden, a defendant must prove invalidity by clear-and-convincing evidence. *See Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 99-114 (2011).

2. The burden of proving invalidity never shifts to the patentee and applies at every stage of the litigation. *See, e.g., Canon Comput. Sys., Inc. v. Nu-Kote Int’l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). Thus, the burden applies even where the patentee fails to put on a rebuttal case. *See, e.g., Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1363-64 (Fed. Cir. 2018).

3. Overcoming the presumption of validity is “especially difficult” where a defendant attempts to “rely on prior art that was before the patent examiner during prosecution.” *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004).

B. Conclusions of Law

4. Cipla failed to prove by clear-and-convincing evidence that the Asserted Claims of the ’289, ’587, and ’808 Patents are invalid.

II. Person of Ordinary Skill in the Art

A. Legal Standards

5. The person of ordinary skill in the art (“POSA”) is a “theoretical

¹ To the extent any of the following issues are deemed issues of fact, Teva incorporates such issues into its Proposed Findings of Fact.

construct” and “is not descriptive of some particular individual.” *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty., Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997) (quoting *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 963 (Fed. Cir. 1986)).

6. Factors relevant to determining a POSA’s attributes include “(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256-58 (Fed. Cir. 2007) (quoting *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)).

7. A POSA is not limited to a single individual from a single discipline. Where the relevant factors reflect that the problem in the pertinent art would involve multiple disciplines, a POSA would consist of a team of individuals combining the knowledge, education, and experience of each of those disciplines. *See, e.g., AstraZeneca Pharms. LP v. Anchen Pharms., Inc.*, C.A. No. 10-1835-JAP-TJB, 2012 WL 1065458, at *19 (D.N.J. Mar. 29, 2012) (“The POSA may be a composite of different types of individuals.”) (citing *Medinol Ltd. v. Guidant Corp.*, 341 F. Supp. 2d 301 (S.D.N.Y. 2004); *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216, 228 n.6 (W.D.N.Y. 2003)); *Novartis Pharms. Corp. v. Noven Pharms., Inc.*, 125 F. Supp. 3d 474, 478 (D. Del. 2015) (similar).

B. Conclusions of Law

8. A POSA for the Asserted Claims of the ’289, ’587, and ’808 Patents

would have had the skills, education, and expertise of a team of individuals working together to research, develop, and manufacture an inhalation aerosol product with a dose counter. Such a team would have included individuals with master's degrees in mechanical engineering, design engineering, or related fields, with at least two years of post-graduate experience in developing inhalation aerosol products, or bachelor's degrees in similar fields of study, with a commensurate increase in their years of postgraduate experience. Such a team also would have been familiar with a variety of issues relevant to researching, developing, and manufacturing inhalation aerosol products with dose counters. The team also would have had access to an individual with a medical degree and experience in treating patients with inhalation aerosol devices.

III. Nonobviousness

A. Legal Standards

9. Under 35 U.S.C. § 103(a), a patent would have been obvious only if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

10. In determining whether a patent would have been obvious, a factfinder must consider (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the pertinent art,

and (4) any secondary considerations (i.e., objective indicia) of nonobviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). A determination of obviousness requires consideration of all four factors, “and it is error to reach a conclusion of obviousness until all those factors are considered.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (citing *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012)).

11. Nonobviousness “shall not be negated by the manner in which the invention was made.” 35 U.S.C. § 103(a). Thus, a party alleging obviousness cannot rely on the inventor’s own path to the invention. *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) (“The inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the [POSA] would have followed, as evidenced by the pertinent prior art.”); *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) (“[T]he path that leads an inventor to the invention is expressly made irrelevant to patentability by statute.”). Instead, “the proper analysis requires a form of amnesia that ‘forgets’ the invention and analyzes the prior art and understanding of the problem at the date of invention.” *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1379 (Fed. Cir. 2012).

12. “[O]bviousness determinations based on conclusory and unsupported expert testimony” are inadequate because “crediting such testimony risks allowing the challenger to use the challenged patent as a roadmap to reconstruct the claimed

invention using disparate elements from the prior art—i.e., the impermissible *ex post* reasoning and hindsight bias that *KSR* warned against.” *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019).

13. An obviousness analysis must “avoid even a hint of hindsight.” *Cheese Sys., Inc. v. Tetra Pak Cheese & Powder Sys., Inc.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013). A conclusion of obviousness “cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” *Id.* (citation omitted). Courts must avoid the temptation to use the claimed invention itself as roadmap for scanning the prior art and selecting elements that could be combined to piece the invention together. *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1351-52 (Fed. Cir. 2014) (“[F]or reviewing the prior art, selecting the closest teachings, and combining them in the way the invention cannot be used as a roadmap to review the prior art, select the closest teachings, and piece them together like a puzzle to fit what is claimed. Thus, “[i]t is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (citation omitted).!

14. Obviousness must be determined based on “the prior art as a whole.” *See, e.g., Impax Labs. Inc. v. Lannet Holdings Inc.*, 893 F.3d 1372, 1380-81 (Fed. Cir. 2018); *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011). “Where

the prior art contains ‘apparently conflicting teachings’ (i.e., where some references teach the combination and others teach away from it) each reference must be considered,” including “the degree to which one reference might accurately discredit another.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991)). It is impermissible to “pick and choose” elements of references to consider. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1348 (Fed. Cir. 2008) (citation omitted).

15. Inventions “almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l*, 550 U.S. at 418-19. Thus, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 418.

16. Instead, to establish obviousness, a defendant must generally prove, by clear-and-convincing evidence, that a POSA (1) would have had an affirmative reason or motivation to modify or combine the teachings of the relevant prior art references to practice the claimed invention and (2) would have had a reasonable expectation of success in doing so. *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018); *In re Cyclobenzaprine*, 676 F.3d at 1068-69.

17. Motivation to combine and expectation of success are “two different legal concepts.” *Endo Pharms. Inc. v. Actavis LLC*, 922 F.3d 1365, 1376 n.11 (Fed. Cir. 2019) (citation omitted). Thus, (1) proving a reason or motivation to combine and (2) proving a reasonable expectation of success are two independent requirements for

establishing obviousness—a defendant cannot satisfy its burden by proving one but not the other. *Id.*; see, e.g., *Samsung Elecs. v. Elm 3DS Innovations*, 925 F.3d 1373, 1384 (Fed. Cir. 2019) (reason or motivation insufficient without reasonable expectation of success); *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (testimony that POSA “could combine these references, not that they would have been motivated to do so” was insufficient to prove obviousness).

1. Reason or Motivation to Select, Modify, and Combine

18. A defendant must prove more than just a general reason or motivation to combine two references—the challenge must prove a motivation to make the *particular combination of elements* from those references on which its obviousness theory depends. See *St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232, 1242-43 (Fed. Cir. 2020) (affirming decision rejecting obviousness challenge, where challenger proved that there was a motivation to combine two references, but *failed* to prove that a POSA would have had a reason to make the “*particular combination*” proposed) (emphasis added). Where its obviousness theory depends on it, the defendant must explain *why* a POSA would have selected *some* features from a reference for combination, *but not others*. *Id.* (affirming nonobviousness decision where challenger failed to show why a POSA “when replacing Bessler’s valve with Johnson’s valve would remove the leaflet portion of B[e]ssler’s valve but retain the cuff portion.”). This is consistent with the principle that a defendant must prove that the POSA “would have combined elements from specific references *in the way the claimed invention*

does.” *ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012).

19. Whether a POSA would have had a reason or motivation to achieve the claimed invention includes **both** whether a POSA would have had a reason or motivation to modify or combine elements from multiple prior art references **and** whether a POSA would have selected those “particular references in order to combine their elements” in the first place. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1337 (Fed. Cir. 2016). “The real question is whether [a POSA] would have plucked one reference out of the sea of prior art . . . and combined it with [elements of another reference] to address some need present in the field,” not “whether a [POSA], with two (and only two) references sitting on the table in front of him, would have been motivated to combine . . . the references in a way that renders the claimed invention obvious.” *Id.* Thus, the Federal Circuit “forbids the use of hindsight in the selection of references that comprise the case of obviousness.” *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) (“Because the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of Rouffet’s invention to make the combination, this court infers that the examiner selected these references with the assistance of hindsight.”).

20. For a reason or motivation to have existed, a POSA must have believed not only that invention would have been possible, but that it would have been “on

balance,” desirable. *See, e.g., Impax Labs.*, 893 F.3d at 1381 (“Based on the record before us, we do not find that the court clearly erred in concluding that at the time, zolmitriptan’s known significant reliance on its active metabolite would have, on balance, dissuaded [a POSA] from making nasal formulations of zolmitriptan.”); *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 (Fed. Cir. 2000) (“Trade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter.”).

21. References in a proposed combination must be viewed for all their teachings, without selectively picking out those disclosures helpful to the obviousness theory and ignoring contradictory ones. *Arctic Cat v. Bombardier Recreational Prods., Inc.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017) (“Evidence suggesting reasons to combine cannot be viewed in a vacuum apart from evidence suggesting reasons not to combine. In this case, the same reference suggests a reason to combine, but also suggests reasons that a skilled artisan would be discouraged from pursuing such a combination.”). Thus, “[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.” *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986) (quoting *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965)).

22. A reference “teach[es] away” from an invention “when a person of

ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path that was taken by the applicant.” *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1343 (Fed. Cir. 2011) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). “‘Teaching away’ does not require that the prior art foresaw the specific invention that was later made, and warned against taking that path. It is indeed of interest if the prior art warned against the very modification made by the patentee, but it is not the sole basis on which a trier of fact could find that the prior art led away from the direction taken by the patentee.” *Id.* (“[T]he jury could find, based on the expert testimony, that prior Swiss-style machines taught away from embracing vibrations to improve cutting accuracy because all prior machines improved accuracy by dampening vibrations.”).

23. Evaluation of a POSA’s reasons and motivations must be tethered to the asserted prior art; thus, if a purported combination or modification would “change the principles under which [a reference] operates,” that combination or modification would **not** have been obvious. *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020); *see also Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App’x 755, 759 (Fed. Cir. 2015) (“[A] change in a reference’s ‘principle of operation’ is unlikely to motivate a person of ordinary skill to pursue a combination with that reference.”).

24. “[K]nowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373 (Fed. Cir. 2008). Thus, conclusory expert assertions

regarding a POSA's reasons and motivations "without an explanation" of how specific "references would yield a predictable result" are "not sufficient" and "fraught with hindsight bias." *ActiveVideo*, 694 F.3d at 1327. More generally, assertions regarding a POSA's knowledge and skill "cannot be used as a wholesale substitute for reasoned analysis and evidentiary support." *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016).

25. "[A]n invention can often be the recognition of a problem itself." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013) (citing *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371 (Fed. Cir. 2004)). An invention would not have been obvious if the evidence shows that the inventors "recognized and solved" "a problem that the prior art did not recognize." *Id.*

26. Thus, when evaluating motivation, the court must frame the issue in a way that avoids an overly narrow statement of the problem to be solved, which can reflect "a form of prohibited reliance on hindsight, [because] [o]ften the inventive contribution lies in defining the problem in a new revelatory way." *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 859 (Fed. Cir. 2015) (alterations in *Insite*). "Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness." *Id.*

2. Reasonable Expectation of Success

27. Proving obviousness further requires proving that a POSA would have had a reasonable expectation of success in achieving the claimed invention. *See In re*

Cyclobenzaprine, 676 F.3d at 1068-69. To have had such an expectation, a POSA must have been “motivated to do more than merely to ‘vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.’” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (quoting *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)). Similarly, a POSA must have had a reason or motivation to do more than “to pursue a ‘general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.’” *Id.*

28. An invention would have been “obvious to try” only if the prior art identified the path to the claimed invention and there were “a finite number of identified, predictable solutions” that a POSA would have had reason to try. *KSR Int’l*, 550 U.S. at 421. Put differently, the number of possible solutions, “in the context of the art,” must have been “small or easily traversed.” *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008). When these circumstances were not present, the invention would not have been obvious. *See Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011) (“When a field is ‘unreduced by direction of the prior art,’ and when prior art gives ‘no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful,’ an invention is not obvious to try.”) (citing *Bayer Schering*

Pharms. AG v. Barr Labs., Inc., 575 F.3d 1341, 1350 (Fed. Cir. 2009); *In re O'Farrell*, 853 F.2d at 903).

29. In all cases, a POSA's alleged reasons and expectations regarding the prior art must be assessed with respect to the actual needs in the pertinent art. *See KSR Int'l*, 550 U.S. at 421. In other words, if a POSA would not have believed that the invention would solve those needs, the invention would not have been obvious. *See L.A. Biomedical Rsch. Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co.*, 849 F.3d 1049, 1064 (Fed. Cir. 2017) ("Importantly, without a sound explanation for doing otherwise, . . . the expectation-of-success analysis must match the highly desired goal, not switch to a different goal that may be a less challenging but also less worthwhile pursuit.") (citing *Institut Pasteur & Universite Pierre et Marie Curie v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013)).

30. "A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out." *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995). Thus, a party cannot establish that an invention would have been obvious merely by asserting that a POSA "would have arrived at the claimed invention through routine experimentation." *Alcon Rsch., Ltd. v. Watson Labs., Inc.*, C.A. No. 15-1159-GMS, 2018 WL 1115090, at *23 (D. Del. Mar. 1, 2018) (quoting *In re Stepan Co.*, 868 F.3d 1342, 1346 (Fed. Cir. 2017)).

3. Distinct from Other Requirements

31. Under 35 U.S.C. § 112 ¶ 1, a patent's "specification shall contain a

written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”

32. Sections 103(a) and 112 impose independent requirements. Whereas the former turns on “whether the claimed invention would have been obvious in view of the *prior art*,” the latter “turns on whether the skilled artisan, after reading the specification, would be able to make and use the claimed invention without undue experimentation, based on the ordinary skill in the art.” *Allergan, Inc. v. Sandoz Inc.*, 769 F.3d 1293, 1310 (Fed. Cir. 2015). Thus, there is “no tension” in a conclusion that a claim satisfies both requirements—otherwise, no patent would be valid. *Id.*

B. Conclusions of Law

33. Cipla failed to prove by clear and convincing evidence that the Asserted Claims would have been obvious under 35 U.S.C. § 103(a).

1. '289 Patent

34. Cipla failed to prove by clear and convincing evidence that claims 1, 2, 4, 6, and 7 would have been obvious under 35 U.S.C. § 103(a) over International Patent Publication No. WO 2007/124406 (the “406 Publication”) in combination with International Publication No. WO 03/101514 (the “514 Publication”).

35. Cipla failed to prove by clear-and-convincing evidence that a POSA

would have had a reason or motivation to select, modify, or combine the '406 and/or the '514 Publications to achieve inventions of claims 1, 2, 4, 6, and 7 of the '289 Patent.

36. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reasonable expectation of success in selecting, modifying, or combining the '406 and/or '514 Publications to achieve the inventions of claims 1, 2, 4, 6, and 7 of the '289 Patent.

2. '587 Patent

37. Cipla failed to prove by clear and convincing evidence that claims 1, 2, 4, 6, 7, and 12 would have been obvious under 35 U.S.C. § 103(a) over the '406 Publication in combination with the '514 Publication.

38. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reason or motivation to select, modify, or combine the '406 and/or the '514 Publications to achieve the inventions of claims 1, 2, 4, 6, 7, and 12 of the '587 Patent.

39. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reasonable expectation of success in selecting, modifying, or combining the '406 and/or '514 Publications to achieve the inventions of claims 1, 2, 4, 6, 7, and 12 of the '587 Patent.

3. '808 Patent

40. Cipla failed to prove by clear and convincing evidence that claim 28 of

the '808 Patent would have been obvious under 35 U.S.C. § 103(a) over the '406 Publication in combination with the knowledge of the POSA.

41. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reason or motivation to select, modify, or combine the '406 Publication and/or the knowledge of a POSA to achieve the inventions of claim 28 of the '808 Patent.

42. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reasonable expectation of success in selecting, modifying, or combining the '406 Publication and/or the knowledge of a POSA to achieve the inventions of claim 28 of the '808 Patent.

43. Cipla failed to prove by clear and convincing evidence that claim 28 of the '808 Patent would have been obvious under 35 U.S.C. § 103(a) over International Patent Publication No. WO 2008/119552 (the "552 Publication") in combination with the knowledge of a POSA.

44. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reason or motivation to select, modify, or combine the '552 Publication and/or the knowledge of a POSA to achieve the inventions of claims 28 of the '808 Patent.

45. Cipla failed to prove by clear-and-convincing evidence that a POSA would have had a reasonable expectation of success in selecting, modifying, or combining the '552 Publication and/or the knowledge of a POSA to achieve the

inventions of claim 28 of the '808 Patent.

4. Remedies

46. Teva is entitled to a declaration and judgment that the Asserted Claims of the '289, '587, and '808 Patents are not invalid.

47. Cipla is not entitled to a declaration and judgment that the Asserted Claims of the '289, '587, and '808 Patents are invalid.

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Respectfully submitted,

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